IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Walter Newman	
Application No.:	10/717,984	Group Art Unit: 1644
Filed:	November 20, 2003	Examiner: Maher M. Huddad Ph.D.
Confirmation No.:	8906	
Title:	HMGB1 COMBINATION THERAPIES	

CERTIFICATE OF MAILING OR TRANSMISSION

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

05/11/2006 FFANAEIA 00000060 10717984
01 FC:1806 180.00 OP

Sir:

This Information Disclosure Statement is submitted:

[ ] under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

[ ] under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

[X] under 37 CFR 1.97(c) together with either:

[ ] a Statement under 37 CFR 1.97(e), as checked below, or

[X] a $180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

[ ] under 37 CFR 1.97(d) together with:

[ ] a Statement under 37 CFR 1.97(e), as checked below, and

[ ] a $180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

[ ] under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

[ ] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

[ ] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)
Applies to original applications (other than design) filed on or after May 29, 2000

[ ] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

[X] Enclosed herewith is form PTO-1449:

[X] Copies of the cited references [B1-B9 and C1-C83] are enclosed.

[X] Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

[ ] Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

[X] The listed references C1-3 were cited in the enclosed International Search Report and references B1 and C4-7 were cited in the enclosed Supplementary Partial European Search Report in counterpart foreign applications.

[X] The "concise explanation" requirement (non-English references) for reference(s) B6 and B9 under 37 CFR 1.98(a)(3) is satisfied by:

[ ] the explanation provided on the attached sheet.

[ ] the explanation provided in the Specification.

[ ] submission of the enclosed International Search Report.

[ ] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

[X] the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's Initials

_____ U.S. Patent Application No. 10/147,447, by Kevin J. Tracey, *et al.*, filed May 15, 2002, Docket No.: 3268.1001-001

_____ U.S. Patent Application No. 10/300,072, by Kevin J. Tracey, *et al.*, filed November 20, 2002, Docket No.: 3268.1001-005 and current claims.

_____ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

_____ _____

Examiner Date

[X] A copy of each above-cited application, including the current claims, is enclosed.

[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[X] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[ ] Please charge Deposit Account 08-0380 in the amount of $[ ]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated: May 8, 2006

PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 3258.1008-001	APPLICATION NO. 10/717,984
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	FIRST NAMED INVENTOR Walter Newman	FILING DATE November 20, 2003
May 8, 2006	EXAMINER Maher M. Huddad Ph.D.	CONFIRMATION NO. 8906 / GROUP 1644
(Use several sheets if necessary)		

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	5,594,114	01/14/1997	Goodearl, A. D. J., *et al.*
	A2	6,303,321 B1	10/16/2001	Tracey, K. J.
	A3	6,448,223 B1	09/10/2002	Tracey, K. J. and Wang, H.
	A4	6,468,533 B1	10/22/2002	Tracey, K. J. and Wang, H.
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	A9	6,171,779 B1	01/09/2001	Chada, K.K., *et al.*
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(Use several sheets if necessary)	EXAMINER / CONFIRMATION NO. / GROUP	
	Maher M. Huddad Ph.D. / 8906 / 1644	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES	TRANSLATION NO
	B1	EP 1 033 401 A2	09/06/2000	GENSET		
	B2	WO 00/47104 A2	08/17/2000	The Picower Institute for Medical Research		
	B3	WO 99/59609 A2	11/25/1999	Bartorelli, A.		
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	B5	WO 2004/004763 A2	01/15/2004	Bianchi, M. E., *et al.*		
	B6	JP 62-166897	07/23/1987	Toyo Soda Mfg Co. Ltd., *et al.*		X
	B7	EP 1 079 849 B1	01/02/2002	Bartorelli, A.		
	B8	WO 96/25493 A1	08/22/1996	K.U. Leuven Research & Development		
	B9	WO 97/23611 A2	07/03/1997	Bullerdiek, J.		X
	B10					
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		OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*
	C1	Wang, H., *et al.*, "HMG-1 as a Late Mediator of Endotoxin Lethality in Mice," *Science*, *285*:248-251 (1999).
	C2	Andersson, U., *et al.*, "High Mobility Group 1 Protein (HMG-1) Stimulates Proinflammatory Cytokine Synthesis in Human Monocytes," *J. Exp. Med.*, *192*(4):565-570 (2000).
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	C4	Rogalla, P., *et al.*, "Mapping and molecular characterization of five HMG1-related DNA sequences," *Cytogenet. Cell Genet.*, *83*:124-129 (1998).
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	C8	Abaza, M.-S. I. and Atassi, M. Z., "Effects of Amino Acid Substitutions Outside an Antigenic Site on Protein Binding to Monoclonal Antibodies of Predetermined Specificity Obtained by Peptide Immunization: Demonstration with Region 94-100 (Antigenic Site 3) of Myoglobin," *J. Protein Chem. 11(5)*:433-444 (1992).
	C9	Ayer, L. M., *et al.*, "Antibodies to HMG Proteins in Patients With Drug-Induced Autoimmunity," *Arthritis Rheum.*, *37*(1):98-103 (1994).
	C10	Banks, G. C., *et al.*, "The HMG-I(Y) A·T-hook Peptide Motif Confers DNA-binding Specificity to a Structured Chimeric Protein," *J. Biol. Chem.*, *274*(23):16536-16544 (1999).
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		OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*
	C12	Bianchi, M. E., *et al.*, "The DNA Binding Site of HMG1 Protein is Composed of Two Similar Segments (HMG Boxes), Both of Which Have Counterparts in Other Eukaryotic Regulatory Proteins," *EMBO J.*, *11*(3):1055-1063 (1992).
	C13	Bianchi, M. E., *et al.*, "Specific Recognition of Cruciform DNA by Nuclear Protein HMG1," *Science, 243*:1056-1059 (1989).
	C14	Bustin, M., "Revised Nomenclature for High Mobility Group (HMG) Chromosomal Proteins," *Trends Biochem. Sci.*, *26*:152-153 (2001).
	C15	Bustin, M., *et al.*, "Antigenic Determinants of High Mobility Group Chromosomal Proteins 1 and 2," *Biochem.*, *21*:6773-6777 (1982).
	C16	Bustin, M., *et al.*, "Immunological Relatedness of High Mobility Group Chromosomal Proteins from Calf Thymus," *J. Biol. Chem.*, *253*(5):1694-1699 (1978).
	C17	Chou, D. K. H., *et al.*, "Identity of Nuclear High-Mobility-Group Protein, HMG-1, and Sulfoglucuronyl Carbohydrate-Binding Protein, SBP-1, in Brain," *J. Neurochem.*, *77*:120-131 (2001).
	C18	Colman, P. M., "Effects of Amino Acid Sequence Changes on Antibody-Antigen Interactions," *Res. Immunol.*, *145*(1):33-36 (1994).
	C19	Czura, C., *et al.*, "Dual Roles for HMGB1: DNA Binding and Cytokine," *J. Endotoxin Res.*, *7*(4):315-321 (2001).
	C20	Daston, M. M. and Ratner, N., "Expression of P30, a Protein with Adhesive Properties in Schwann Cells and Neurons of the Developing and Regenerating Peripheral Nerve," *J. Cell Biol.* *112*(6):1229-1239 (1991).
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	C23	Freeman, B. D., *et al.*, "The Role of Inflammation in Sepsis and Septic Shock: A Meta-Analysis of Both Clinical and Preclinical Trials of Anti-Inflammatory Therapies," in *Inflammation: Basic Principals and Clinical Correlates* (John I. Gallin and Ralph Snyderman eds., Lippincott, Williams & Wilkins, Philadelphia, 3rd ed.), pp 965-975 (1999).
	C24	Imamura, T., *et al.*, "Interaction with p53 Enhances Binding of Cisplatin-Modified DNA by High Mobility Group 1 Protein," *J. Biol. Chem., 276*(10):7534-7540 (2001).
	C25	Ise, T., *et al.*, "Transcription Factor Y-Box Binding Protein 1 Binds Preferentially to Cisplatin-Modified DNA and Interacts With Proliferating Cell Nuclear Antigen," *Cancer Res., 59*:342-346 (1999).
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	C28	Landsman, D. and Bustin, M., "A Signature for the HMG-1 Box DNA-Binding Proteins," *BioEssays*, *15*(8):539-546 (1993).
	C29	Lederman, S., *et al.*, "A Single Amino Acid Substitution in a Common African Allele of the CD4 Molecule Ablates Binding of the Monoclonal Antibody OKT," *Mol. Immunol., 28*(11):1171-1181 (1991).
	C30	Ma, W., *et al.*, "Detection of Anti-neutrophil Cytoplasmic Antibodies in MRL/Mp-*lpr/lpr* Mice and Analysis of Their Target Antigens," *Autoimmunity*, *32*(4):281-291 (2000).
	C31	Melloni, E., *et al.*, "Identity in Molecular Structure Between 'Differentiation Enhancing Factor' of Murine Erithroleukemia Cells and the 30 kD Heparin-Binding Protein of Developing Rat Brain," *Biochem. Biophys. Res. Commun., 210(1)*:82-89 (1995).
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	C33	Merenmies, J., *et al.*, "30-kDa Heparin-Binding Protein of Brain (Amphoterin) Involved in Neurite Outgrowth," *J. Biol. Chem.*, *266*(25):16722-16729 (1991).
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	C35	Mohan, P. S., *et al.*, "Sulfoglycolipids Bind to Adhesive Protein Amphoterin (p30) in the Nervous System," *Biochem. Biophys. Res. Commun.*, *182*(2):689-696 (1992).
	C36	Parkkinen, J. and Rauvala, H., "Interactions of Plasminogen and Tissue Plasminogen Activator (t-PA) with Amphoterin," *J. Biol. Chem.*, *266*(25):16730-16735 (1991).
	C37	Parkkinen, J., *et al.*, "Amphoterin, the 30-kDa Protein in a Family of HMG1-type Polypeptides," *J. Biol. Chem., 268*(26):19726-19738 (1993).
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	C39	Rauvala, H. and Pihlaskari, R., "Isolation and Some Characteristics of an Adhesive Factor of Brain That Enhances Neurite Outgrowth in Central Neurons," *J. Biol. Chem., 262*(34):16625-16635 (1987).
	C40	Rauvala, H., *et al.*, "The Adhesive and Neurite-Promoting Molecule p30: Analysis of the Amino-Terminal Sequence and Production of Antipeptide Antibodies That Detect p30 at the Surface of Neuroblastoma Cells and of Brain Neurons," *J. Cell Biol., 107*(6):2293-2305 (1988).
	C41	Romani, M., *et al.*, "Serological Analysis of Species Specificity in the High Mobility Group Chromosomal Proteins," *J. Biol. Chem., 254*(8):2918-2922 (1979).
	C42	Salmivirta, M., *et al.*, "Neurite Growth-Promoting Protein (Amphoterin, p30) Binds Syndecan," *Exp. Cell Res.*, *200*:444-451 (1992).
	C43	Scaffidi, P., *et al.*, "Release of Chromatin Protein HMGB1 by Necrotic Cells Triggers Inflammation," *Nature*, *418*:191-195 (2002).

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OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*		
	C44	Sobajima, J., *et al.*, "Prevalence and Characterization of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies (P-ANCA) Directed Against HMG1 and HMG2 in Ulcerative Colitis (UC)," *Clin. Exp. Immunol., 111*:402-407 (1998).
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	C47	Sobajima, J., *et al.*, "High Mobility Group (HMG) Non-Histone Chromosomal Proteins HMG1 and HMG2 are Significant Target Antigens of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies in Autoimmune Hepatitis," *Gut, 44*:867-873 (1999).
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	C52	Vanderbilt, J. N. and Anderson, J. N., "Monoclonal Antibodies as Probes for the Complexity, Phylogeny, and Chromatin Distribution of High Mobility Group Chromosomal Proteins 1 and 2," *J. Biol. Chem., 260*(16):9336-9345 (1985).
	C53	Wang, H., *et al.*, "Proinflammatory Cytokines (Tumor Necrosis Factor and Interleukin 1) Stimulate Release of High Mobility Group Protein-1 by Pituicytes," *Surgery, 126*(2):389-392(1999).

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	Maher M. Huddad Ph.D.	8906	1644

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	C54	Wen, L., *et al.*, "A Human Placental cDNA Clone that Encodes Nonhistone Chromosomal Protein HMG-1," *Nucleic Acids Res., 17*(3):1197-1213 (1989).
	C55	Yamada, S., *et al.*, "High Mobility Group Protein 1 (HMGB1) Quantified by ELISA with a Monoclonal Antibody That Does Not Cross-React with HMGB2," *Clin. Chem., 49*(9):1535-1537 (2003).
	C56	Zhang, M and Tracey, K. J., "Tumor Necrosis Factor," in *The Cytokine Handbook*, (Academic Press Limited), Third Edition, pp. 517-548 (1998).
	C57	GenBank Accession No. AC010149, "Homo sapiens BAC clone RP11-395A23 from 2, complete sequence," (2001) [online] [retrieved on 4/18/2006]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
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	C59	GenBank Accession No. AF076674, "Homo sapiens high mobility group 1-like protein L1 (HMG1L1) retropseudogene sequence," (1999) [online] [retrieved on 4/18/2006]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
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	C61	GenBank Accession No. NG_000897, "Homo sapiens high-mobility group (nonhistone chromosomal) protein 1-like 5 (HMG1L5) pseudogene on chromosome 3," (2006) [online] [retrieved on 4/18/2006]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
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